

JUN 13 2001

PROTECTION GLOVES SDN.BHD.
LOT NO. 236, BATU 2 ½,
JALAN YONG PENG,
85400 CHAAH, JOHOR,
MALAYSIA.
TEL : (60) 7-9263909
FAX : (60) 7-9264127

K010854

Chlorinated Powder – Free
Latex Examination Glove (Blue, Green)

510(k) SUMMARY
Of Safety and Effectiveness

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

1. [807.92 (c)] Separate Document

2. [807.92 (a)] Applicant : Protection Gloves Sdn. Bhd.
Lot No 236, Batu 2 ½,
Jalan Yong Peng, 85400 Chaah,
Johor, Malaysia.
Phone : (60) 7-9263909
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Contact : Mr. Richard Chooi
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3. [CFR 880.6250] **Date Summary Prepared : 16 March, 2001**
Name Of Device :

♦ Proprietary Name : Multiple
♦ Common Name : Powder Free Chlorinated
(Blue, Green)
♦ Classification : Class 1 : Patient examination glove (per 21CFR
880.6250)

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4. [807.92 (c) (4)] **Description :**

This Class 1 patient examination glove (80 LYY) is powder-free and meets all the requirements of ASTM Standard D 3578-00 with the present of Chlorination process.

5. [807.92 (c) (5)] **Intended Use :**

A glove is worn on the hand of healthcare and similar personnel to prevent contamination between healthcare personnel and the patient's body, fluids, waste or environment.

6. [807.92 (c) (6)] **Technological Characteristics of applicant device ; non-clinical performance data :**

Gloves comply with ASTM D 3578-00 Standard and the FDA Water Leak Test.

- A. Gloves comply with ASTM D 3578-00 and 1,000 ml Water Leak requirement.
- B. The powder-free assessment which follows is based upon ASTM D 6124-2000 test method and meet powder limit of ≤ 2 mg/glove :

C. Biocompatibility As recommended by the Tripartite Guidance on Biocompatibility Of Medical Devices.	Applicant Device
	Pass / Fail
♦ <u>Primary Dermal Irritation</u> Consumer Product Safety Commission, Title 16, Chapter 11 Part 1500	Pass
♦ <u>Dermal sensitization (Buehler) Study</u> ASTM Standard F 720 – 81 (Reapproved in 1986)	Pass

7. [807.92 (a) (c)] **Non - Clinical performance data :**

A summary of results of non-clinical performance evaluation is presented above. A brief description of these tests follows :

A : Dimensional and Physical Properties

ASTM D 3578-00 specifies the dimensional measurement requirements including thickness to which the Applicant gloves comply, unless otherwise noted.

1,000 ml FDA Water Leak Test consists of attaching a glove over the end of a plastic cylinder and dispensing 1,000 ml of water into the glove. Leaks within a two-minute period are recorded as failures. Testing is performed according to 21 CFR 800.20 (b) (1). Sampling is performed utilizing ISO-2589-1 or an increased sampling tightness when deemed appropriate. Applicant glove and K 945164 meet this FDA requirement.

B : the powder-free test method is an assay, following ASTM D 6124-2000 were carried out, However no standards have been set by the FDA.

C : Biocompatibility

Primary Dermal Irritation. The testing is performed according to the regulations of the Consumer Product Safety Commission, Title 16, Chapter 11, Part 1500. The purpose of the study is to determine the dermal irritation potential of the glove to the shaved intact and abraded skin on the backs of albino rabbits. Appropriate controls were conducted. Applicant glove [Chlorinated Powder Free Examination Glove, High Risk (Blue, Green)] showed no significant irritancy potential.

Dermal Sensitization (Buehler) Study. This study is performed on young adult Hartley Guinea Pigs (male & female) per extract to determine the sensitization potential of the gloves. Appropriate controls were conducted. Applicant Gloves [Chlorinated Powder Free Examination Glove High Risk (Blue, Green)] showed no significant sensitization potential.

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8. [807.92 (b) (3)] **Conclusions drawn from the non-clinical tests in 6 and 7 above**

The applicant glove meets or exceeds ASTM standards, FDA pinhole requirements and labeling claims as demonstrated in 6 and 7 above.

9. [807.92 (d)] **Other information deemed necessary by the FDA**

No other information has been requested at this time.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 13 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Richard Chooi
Business Development Manager
Protection Gloves Sdn. Bhd.
Lot No. 236, Batu 2 1/2,
Jalan Yong Peng
85400 Chaah, Johor,
MALAYSIA

Re: K010854
Trade/Device Name: Chlorinated Powder-Free Latex
Examination Gloves, (Blue, Green)
Regulation Number: 880.6250
Regulatory Class: I
Product Code: LYY
Dated: March 16, 2001
Received: March 22, 2001

Dear Mr. Chooi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

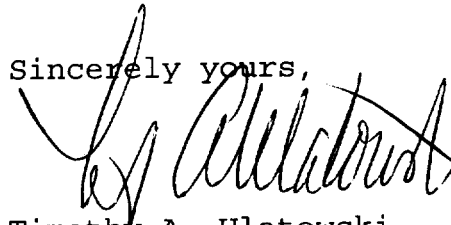
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510 (k) Number (if known) : K010854 *

Device Name : Chlorinated Powder - Free Latex Examination Gloves (Blue, Green)

Indication For Use :

To be worn on the hand of healthcare and similar personnel to prevent contamination between healthcare personnel and the patient's body, fluids, waste or environment.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____

OR

Over – The- Counter Use X

(Per 21CFR 801.109)

(Optional Format 1-2-96)

* New Submission

Chun S. Lim
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010854